

Memorandum

Date

July 22, 1983

From

Head, Screening Operations Section, DEB, DTP, DCT, NCI

Subject

Revision of Protocol 8

То

All <u>In Vivo</u> Screeners

Attached you will find a revision of Protocol 8, "Animals and Animal Care". This is intended to replace, in its entirety, the Protocol 8 published in the 1972 Protocols. Please consider this document effective immediately.

Thank you for your attention to this matter.

Betty J Abbott

Attachment

Animals and Animal Care

8.100 SOURCES OF ANIMALS

Animals will be supplied by the Animal Genetics and Production Branch (AG&PB), DTP, DCT, NCI. In some cases animals may be purchased from sources approved by the AG&PB. Purchased animals shall be obtained only from these sources with written instruction by the Project Officer/Contracting Officer.

8.200 STANDARDS FOR ANIMAL CARE AND USE

The care and use of laboratory animals will comply with all Federal /1, state laws and regulations /2 and with the Code of Federal Regulations involving the Use of Laboratory Animals /3.

8.300 ANIMAL FACILITY

The design and physical condition of the facility must be such as to assure that a controlled and protective environment is provided for the animals and that the many variables that could affect the results of a test are precisely stabilized. The functional areas, services areas, construction features of the facility, and animal care practices are to be consistent with the intent of the recommendations in the NIH "Guide"/4.

- 8.310 Minimally the following separate animal room capabilities are to be provided: (a) quarantine, (b) holding, (c) testing, and (d) tumor donor. See also 8.520.
- 8.320 Holding Rooms: These rooms are to be used to maintain animals prior to their use for testing. The holding period may extend to three weeks for healthy animals that appear to gain weight slowly. If they are still questionable, request a decision from your Project Officer on extending the holding period. Unsatisfactory animals in groups of 50 or more shall not be discarded without prior consultation with your Project Officer.
- 8.330 Testing Rooms: These rooms shall be used only for animals that are being used in a test. These rooms shall not be used for the storage of large quantities of food, bedding, caging equipment, laboratory equipment, etc. A testing room should house only one species. Two or more strains of a species are acceptable.
- 8.340 Tumor Donor Rooms: These rooms shall be used to maintain only those animals that are used as tumor donors or sentinel animals as requested by the Project Officer.
- 8.350 Animals judged unsatisfactory on receipt for experimental purposes are to be reported to AG&PB. These include underweights (14-16 grams) and those apparently in poor health. Consignees of animals should complete and forward the Weekly Animal Report (Form NIH 5771) as directed by the Project Officer.

- 8.360 Animal rooms will be subjected to periodic inspections by AG&PB personnel as well as by the Project Officer.
- 8.370 Cages: Animal cages shall be made of impervious, corrosion-resistant materials. Only solid bottom cages are to be used. Alternative caging is to be approved by AG&PB.

8.400 ANIMAL HUSBANDRY

The methods for caging, feeding, watering, and identifying the animals; for sanitizing the facility, caging, and equipment; for handling wastes; and for providing care during off hours and emergencies must permit the animals to be maintained in physical comfort and good health and to behave normally.

- 8.410 Each cage shall be provided with a food holder for pelleted rations. The food holders shall be made of corrosion-resistant material. Food shall not be offered on the floor of the cage. An effective vermin control program which does not expose the animals to unnecessary risk from pesticides is required.
- 8.500 ANIMAL QUALITY AND HEALTH

All animals are to be protected from contact with infectious microbes. A person with proper education, training, and experience is to be assigned the responsibility for monitoring the facilities and the animal care program. Adequate veterinary care is to be provided.

- 8.510 Colonies are to be identified by source and are to be monitored microbiologically by qualified diagnostic assistance as directed by AG&PB.
- 8.520 All animals, upon receipt, are to be examined and evaluated, entered in the record system, placed in quarantine, and held for a period of time necessary to ensure that they are healthy. During quarantine, each shipment of animals is observed daily for signs of abnormality and is kept isolated from contact with other animals in the existing colony and from other quarantined shipments. Animals are to be housed separately according to species and source unless objective evidence demonstrates that the animals are not a health hazard to each other if placed in the same room. It is recommended that, within space limitations, all incoming animals be held separately according to source. Further, within space limitations, animals should also be held separately by strain. Limitations to these capabilities should be discussed with Project Officer and/or AG&PB.
- 8.530 All animals are to be observed daily for signs of illness or other abnormalities, and all abnormalities are reported promptly to each laboratory's person responsible for veterinary care. Antibiotics and/or other therapeutic agents are not recommended and under no circumstances are they to be administered to the animals without prior written approval by the AG&PB.

- 8.540 Animals and specimens are to be submitted to diagnostic laboratories as designated and scheduled by AG&PB.
- 8.550 Anesthetics, analgesics, or tranquilizers are to be used, when necessary, to effectively minimize pain or discomfort. Guidelines and consultation concerning choice and use of these drugs are provided/4.
- 8.560 Euthanasia is to be performed by trained personnel in a rapid and humane manner using methods recommended in the report of the AVMA Panel on Euthanasia/5. The method selected shall not in any way alter or damage a tumor associated with the study in progress, nor so change its characteristics as to interfere with the evaluation of the test.

8.600 PERSONNEL QUALIFICATIONS

An adequate number of persons with the qualifications necessary to direct, supervise, conduct, and support the animal care program is to be provided. Continuing formal and on-the-job training is to be encouraged.

8.700 POTENTIAL HAZARDS

Policies governing the handling of potential hazards are to be stated in writing, and should define the method for identifying and controlling hazards. A qualified person is to be authorized to monitor the safe performance of each test.

- 8.710 Animal cages and other equipment that minimize the escape of the test chemical or otherwise contain the potential hazard to the minimum space are to be used when necessary. The degree of containment used should correlate with the degree of hazard.
- 8.720 An occupational health program should be provided for persons working in animal facilities and for others having substantial contact with animals.
- 8.730 Personnel are not to be permitted to eat, drink, or smoke in animal rooms.
- 8.740 As an aid in maintaining high standards of personal cleanliness, clothing, supplies, and facilities, such as showers and locker rooms, should be provided for all persons entering the animal facilities.

8.800 STANDARD OPERATING PROCEDURES (SOP)

Each routine or repetitive operating procedure involving the care and use of animals is described in writing in sufficient detail and clarity as to ensure the uniform performance of the procedure. The written SOP is to be available at each location where the procedure is performed and is subject to review by the Project Officer.

- 8.810 Any significant change in a standard operating procedure must be properly approved by the Principal Investigator, documented and the date of the change recorded.
- 8.820 Records are to be maintained reflecting the completion of each SOP step, identifying the responsible individual and the date of completion.
 - 8.900 GENERAL UTILIZATION

The consignee of animals supplied is urged to maintain close liaison with AG&PB, on quality of animals.

8.910 All requests for animals shall be directed to the AG&PB.

Footnotes to section 8.000:

- /1 Laboratory Animal Welfare Act (PL 89-544). Animal Welfare Act (PL 91-579). Animal Welfare Acts of 1976 (PL 94-279).
- /2 Code of Federal Regulations, Title 9, Subchapter A, Animal Welfare.
- $\frac{3}{2}$ Code of Federal Regulations, Title 41, Subpart 3-4.58.
- "Guide for the Care and Use of Laboratory Animals" DHEW Publication No. (NIH) 78-23 or subsequent revisions.
- /5 Report of the Panel on Euthanasia. J Amer Vet Med Assoc, 1978; 173:59-72.